K003778

JUN - 8 2001

Premarket Notification [510(k)] Summary
Tab 4

DATE

Trade Name: Breast-Board (Multiple)

Common Name: Positioning Device for treating breast cancer

Classification Name: Medical Linear Accelerator Accessory, 90 IYE (per 21 CFR section 892.5050)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: MEDTEC INC. CARBON FIBER BREAST-BOARD, 510(K) # K974703

Device Description:

The main components are a fixed base plate attached to a tilting board where the patient lies. The whole unit is manufactured from Perspex or thin crossed layers of carbon fiber, depending on the preference of the treating physician. When made from this kind of carbon fiber,first the rigidity is maintained thus preventing sagging and the attenuation factor of these boards is less than 1% for an irradiation beam of 18Mev and higher. The tilting board may rest on angled wedges or elevation legs. It may be supplied with a standard buttock rest and standard hand grips.

Intended Use: The breast-board is intended for use in positioning the patients

During simulation or external beam radiation therapy.

Technological Characteristics: See the attached Predicate Comparison Table

Feature #	Feature	Carbon Fiber Breast-Board MEDTEC INC. K974703	Arplay Medical Breast-Board (Multiple) for patient positioning
1	Rigid Fixed baseplate and Tilting Board	Carbon Fiber	Perspex & Carbon Fiber
2	Radiotransluscent	Yes	Yes
3	User Friendly	Yes	Yes
4	Light Weight	Yes	Yes (16.50 lbs)
5	Compatible with CT SCAN tunnel	Yes	Yes with exclusion of elbow-rest
6	Accessories	Standard & optional	Standard & optional
7	Removable lateral panels	No	Yes
8	Headrests for tilting board	Multiple sizes, Polyurethane	Multiple sizes, Polystyrene, & Radiotransluscent polyurethane,
9	Four positioning buttock rest	No	Yes
10	Carbon fiber	moulded	Laid in thin crossed layers
	Adaptable to fit other manufacturers head base plates	No	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2001

Richard Borgi, M.D.
President & CEO
Arplay Medical S.A.
1 Route de Citeaux
21110 Izeure
FRANCE

Re: K003778
Breast-Board (Multiple)
Dated: March 9, 2001
Received: March 14, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Dr. Borgi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K003778

Device Name: Breast Board (Multiple)

Indications for Use:
Devices for positioning the patient on the simulator or treatment couch in order to simulate the treatment or to treat with radiation .

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David C. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003778